REMARKS

The above-identified Application has been carefully reviewed with the Office Action of May 26, 2009, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

The Examiner rejected claim 1 and 4 under 35 U.S.C. § 102(b) as being anticipated by Orgill et al (WO00/16822) as evidenced by The Summary of Safety and Effectiveness for PROLENE soft (2000 Section 7, pages 25-27), hereinafter "PROLENE".

A proper rejection of a claim under 35 U.S.C. §102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990).

Orgill et al discloses a composite mesh consisting of polypropylene (PP) integrated with collagen-glycosaminoglycan (CG) (page 3, lines 9-11). Orgill envisioned that hyaluronic acid can be used as glycosaminoglycan (page 7, lines 31 to page 8, line 3). In example, page 16, lines 5-16, the collagen-glycosaminoglycan can be a lyophilisate.

From example, page 16, lines 5-16, the Applicants are of the opinion that collagen is the main component. Thus, Orgill et al does not disclose a lyophilisate of biocompatible material, which comprises, as its main component, a hyaluronic acid or its derivative.

Furthermore, as acknowledged by the Examiner, nowhere do Orgill et al disclose that the molecular mass of the hyaluronic acid or its derivative has a molecular mass of between 800,000 and 2,000,000 Daltons. Thus claim 1 is novel.

Claim 1 has been limited to *a lyophilisate of a biocompatible material, which comprises, as its main component a lyophilisate of hyaluronic acid or its derivative with a molecular mass of between 800,000 and 2,000,000 Daltons.*

This limitation is guided by the following technical considerations:

1. If the hyaluronic acid molecular mass is too low, the hyaluronic acid lyophilisate disaggregates or breaks down, and
2. If the hyaluronic acid molecular mass is too high, the hyaluronic acid lyophilisate cannot be manufactured because the hyaluronic acid is not homogeneous in solution.

However, it was discovered by the Applicants, that a hyaluronic acid lyophilisate suitable to cover a textile support can be obtained if the molecular mass of the hyaluronic acid is selected in the range [800,000 - 2,000,000] and more preferably in the range [1,200,000 - 1,500,000].

It should be noted that hyaluronic acid is available with a very broad range of molecular mass. For example, WO0106973 discloses that the molecular mass of hyaluronic acid varies from 40 000 to 8,000,000 (page 1, line 14). Thus, the selected range is narrow compared to the wide range of available hyaluronic acid molecular mass.

Accordingly, the Applicants submit that it was not obvious for the skilled practitioner to recognize that there exists a range of hyaluronic acid molecular mass for which it is possible to manufacture a hyaluronic acid lyophilisate to cover a textile support. Thus, claims 1 and 4 are believed to be in condition for allowance.

Claims 1 and 4 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Orgill et al in view of "PROLENE", the Office Action stating that Orgill et al teach a polypropylene mesh with a freeze dried collagen-glycosaminoglycan blend as well as hyaluronic acid as an envisioned glycosaminoglycan and that Orgill et al teach that the polypropelyene mesh Prolene™ as a particular envisioned mesh and that therefore it would have been obvious

to one of ordinary skill in the art at the time that the invention was made to select this particular variety for the invention of Orgill et al.

This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

> The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> (A) Determining the scope and content of the prior art; and
>
> (B) Ascertaining the differences between the claimed invention and the prior art; and
>
> (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

> When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:
>
> (A) The claimed invention must be considered as a whole;
>
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
>
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
>
> (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United Stated Supreme Court decision in KSR INTERNATIONAL CO. V. TELEFLEX INC. ET AL. 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

> In Graham v. John Deere Co. of Kansas City, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in Hotchkiss v. Greenwood, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:

> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Id., at 17–18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

In view of the amendments submitted herewith to claims 1 and 4, it is submitted that claims 1 and 4 are now in condition for allowance over the combination of references in that Orgill et al do not teach a lyophilisate of hyaluronic acid or its derivative with a molecular mass in between 800,000 and 2,000,000 Daltons. Thus this rejection is respectfully traversed in view of the submitted amendments.

Claims 1, 2, and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Orgill et al in view of the "PROLENE" reference as applied to claims 1 and 4 above and further in view of Noishiki (U.S. Patent No. 5,986,168). The Office Action opines that Orgill et al in view of "PROLENE" make obvious a polypropylene mesh composed of single strand threads with lyophilized hyaluronic acid on its surface but that the modification does not explicitly teach the molecular weight of the hyaluronic acid. The Office Action continues stating that Noishiki teaches a prosthetic device with a bioabsorbable material and in particular hyaluronic acid is taught as a known bioabsorbable material and its molecular weight is disclosed by Noishiki, the

molecular weight ranging from 10,000 to 2,000,000 Daltons. The Office Action then concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a hyaluronic acid between 10,000 to 2,000,000 Daltons for the invention of Orgill et al and that the claims are therefore obvious. Applicants respectfully traverse.

Noishiki notes (column 2, lines 4-9) that porous vascular prostheses coated with bioabsobable substances cross-linked with chemical products were known. However, those chemical products used to cross-link the bioabsorbable substances produce undesirable side effects. Thus, Noishiki proposes (column 2, lines 40-47) to use bioabsorbable substances that are insolubilized by physical methods that do not require those chemical agents. A first list of usable physical methods is given column 3, lines 51-58. A second list of bioabsorbable substances that may be used with the physical method of the first list is given in column 5, line 66 to column 6, line 22. This second list includes the hyaluronic acid. It is even stated that the molecular mass of the hyaluronic acid is comprised between 10,000 and 2,000,000. However, the first list does not include lyophilisation. Consequently, Noishiki only teaches that the hyaluronic acid molecular mass should be between 10,000 and 2,000,000 if it is to be used with one of the method of the first list. He does not give any teaching on which molecular mass the hyaluronic acid should have to be used as a lyophilisate.

Accordingly, Noishiki does not contain any suggestion, expressed or implied, that the hyaluronic acid molecular mass should be between 800,000 and 2,000,000 Daltons to be used as a lyophilisate suitable to cover a textile support. There is no indication that the references should be combined in the manner indicated by the Examiner.

Therefore, there is no reason why one, provided with the Orgill et al's teaching would ever be motivated to replace the collagen-glycosaminoglycan lyophilisate by a lyophilisate which comprise as a main component the hyaluronic acid with a molecular mass between 800,000 and 2,000,000 Daltons.

Therefore, claims 1, 2, and 16 are believed to be in condition for allowance. The dependent claims are believed allowable at least for depending from an allowable independent claim.

Claims 1-2, 13-14, and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Orgill et al in view of the "PROLENE" reference as applied to claims 1 and 4 above and further in view of Boone et al (U.S. Patent No. 6,294,170) and Wade et al (U.S. Patent No. 5,632,995). The Orgill et al reference combined with the "PROLENE" reference were deemed as not explicitly teaching the molecular weight of the hyaluronic acid. The Office Action opines that it would have been obvious to combine these referenced because Boone et al teach hyaluronic acid used in a biological context with a molecular weight between 1,000,000 and 2,000,000 Daltons and that Wade et al teach that hyaluronic acid of 1,200,000 Daltons was known for use in a biological context. The Office continues that in light of the molecular weights of hyaluronic acid known for use in biological context and the routine experimentation within the technical grasp of one of ordinary skill in the art, it would have been obvious to combine these references and arrive at the Applicants' invention. The Applicants respectfully traverse.

Boone only deals with the preparation of a pharmaceutical composition including a therapeutically effective amount of at least one of IL-1ra, a variant of IL-1ra or chemical derivative thereof (Column 27, lines 5-9). Hyaluronic acid serves as a vehicle which provides slow release of the pharmaceutical composition (column 28, lines 26-28). Thus Boone only teaches that when hyaluronic acid is used as a vehicle for administrating IL-1ra, a variant of IL-1ra or chemical derivative thereof, its molecular mass is preferably between 1,000,000 and 2,000,000 (column 29, lines 12-17). This teaching does not give any hint on what should be the hyaluronic acid molecular mass when used to build a lyophilisate that cover a textile support.

Wade deals with the administration of MCWE composition effective for increasing reproductive performance of animal or human (column 6, lines 24-26). Wade only teaches that

the MCWE composition may contain hyaluronic acid with a molecular mass between 500,000 and 1,200,000. As previously, such a teaching does not give any hint to the skill artisan on what should be the hyaluronic acid molecular mass when it is used to manufacture a lyophilisate that cover a textile support.

As discussed hereinabove, it is believed that, with the amendments presented herein, that claims 1-2, 13-14, and 16 are in condition for allowance in that there is no suggestion that even if Orgill et al were motivated to look further through 3 additional references to come up with the claimed invention other than through the use of purely hindsight reasoning, using the Applicants' disclosure as a guide. However, in view of the amendments presented herein, it is believed that the amended claims are in condition for allowance and that the dependent claims are also believed allowable at least for depending from an allowable independent claim.

Claims 1, 3, and 17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Orgill et al in view of Kugel (U.S. Patent No. 5,634,931), the Office Action opining that Orgill et al teach a polypropylene mesh with a freeze dried collagen-glycosaminoglycan blend and that hyaluronic acid is an envisioned glycoaminoglycan; that Orgill et al go on to teach a polypropylene mesh as a particular envisioned mesh; and that the hyaluronic acid is taught by Orgill et al to enhance the anti-adhesive properties of the coated structure (see page 8, lines 2-3). The Office admits that the reference does not explicitly teach the presence of a top layer of bi- or tri-dimensional structure in the mesh support, but that Kugel teaches a hernia mesh patch preferably composed of a top and bottom layer of monofilament polypropylene and that each layer as both two and three dimensions. The Office concludes that since the inhibition of non-specific tissue adhesion between the hernia patch and the surrounding organs/tissues is desirable, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the mesh structure of Kugel in the invention of Orgill et al.

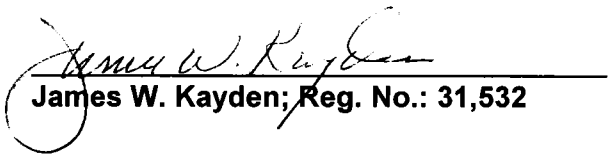
Applicants respectfully traverse. As discussed hereinabove, in view of the amendments to claims 1 and 2, the rejection no longer applies. As Orgill et al do not disclose that the molecular mass of a hyaluronic acid or its derivative as a molecular mass between 800,000 and 2,000,000 Daltons, then there would be no reason for one of ordinary skill in the art to seek to combine the mesh structure of Kugel with the Orgill et al mesh as the skilled artisan would know that Orgill et al was not the correct starting place even if a modification was contemplated. Thus, in view of the amendments submitted herewith, claims 1, 3, and 17 are believed to be in condition for allowance.

Claims 1, 2, and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Orgill et al in view of Noishiki and Kugel. Here, the Office repeats the rejection from the previous section opining that it would be obvious to modify Orgill et al with Kugel to provide both two and three-dimensions and that Noishiki teaches the requisite molecular weight hyaluronic acid. As discussed hereinabove, this rejection is hereby respectfully traversed. As discussed hereinabove, the combination of Orgill et al in view of Kugel and the combination of Orgill et al in view of Noishiki, do not arrive at the present claim 1 in its amended form. Furthermore, the combination of Orgill et al in view of Noishiki and Kugel do not teach that the textile support comprises a top layer selected from a group consisting of a non-woven layer, a woven layer, a knitted layer, and an interlaced layer as stated in claim 15. Thus, for the reasons detailed hereinabove it is submitted that claims 1, 2, and 15 are in condition for allowance over the prior art references cited by the Office.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



James W. Kayden; Reg. No.: 31,532

THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.
Suite 1500
600 Galleria Parkway N.W.
Atlanta, Georgia 30339
(770) 933-9500